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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/820,492

**Applicant(s)**

BAYER ET AL.

**Examiner**

Anita Saidi

**Art Unit**

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**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05/02/2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 4-13, 15-16, 23-55 and 57-61 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 4-13, 15, 16, 23-55 and 57-61 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 05/02/2008.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. This office action is responsive to applicant's arguments filed on May 2, 2008. Examiner acknowledges the amendments to claims 1, 13, 23, 36, 46, 47 and 61. Claims 1, 4-13, 15-16, 23-55 and 57-61 are currently pending.

### ***Response to Arguments***

2. Applicant's arguments, see page 17, lines 5-12 filed May 2, 2008, with respect to rejection of claim 46 under 35 USC § 112 second paragraph has been fully considered and are persuasive. The rejection of claim 46 has been withdrawn.
3. Applicant's arguments, see page 18, lines 9-21, filed May 2, 2008 with respect to the rejection(s) of claim(s) 1 under 35 USC 102(b) as being anticipated by Us 6,468,222 to Mault have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of amended claim and newly found art.
4. Applicant's arguments, see page 18, line 27- page 19, line 2, filed May 2, 2008 with respect to the rejection(s) of claim(s) 4-12 under 35 USC 103(a) as being unpatentable over Mault in view of US 6,319,199 to Sheehan have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of amended claim and newly found art.

5. Applicant's arguments, see page 19, lines 15-24, filed May 2, 2008 with respect to the rejection(s) of claim(s) 13 and 15-16 under 35 USC 102(b) as being anticipated by US 4,274,425 to Lutz have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of amended claim and newly found art.

6. Applicant's arguments, see page 20, lines 12-22, filed May 2, 2008 with respect to the rejection(s) of claim(s) 23, 24-25 and 27-35 under 35 USC 102(b) as being anticipated by Mault have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of amended claim and newly found art.

7. Applicant's arguments, see page 21, lines 8-17, filed May 2, 2008 with respect to the rejection(s) of claim(s) 36 and 37-46 under 35 USC 102(b) as being anticipated by Mault have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of amended claim and newly found art.

8. Applicant's arguments, see page 22, lines 1-19, filed May 2, 2008 with respect to the rejection(s) of claim(s) 34, 45, 47 and 48-53 under 35 USC 102(b) as being anticipated by Mault and 35 USC 103(a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further

consideration, a new ground(s) of rejection is made in view of amended claims and new interpretation of the claims.

Applicant also argues that the claim limitations "D-shaped and V-shaped cross-section" has not been given any weight for the purpose of art rejection of claim 47, however the examiner respectfully disagrees. As indicated in the previous Office action the difference between a D-shaped and V-shaped cross section had been considered a design choice. However the shape of the cross section of the mouthpiece has been given weight and has been addressed in the previous Office action as well as the current Office action as being similar to the teachings of Fig. 23 of Mault. The mouthpiece of Mault has a substantially D-shape but however Mault does not disclose a V-shape cross-section. At the time the applicant's invention was made it would have been an obvious matter of design choice to a person of ordinary skill in the art to have used a different design for the mouthpiece of Mault such as a mouthpiece with a V-shape cross-section rather than a D-shape cross-section. Applicant has not disclosed that choosing a V-shape cross-section for the mouthpiece provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art would have expected Mault's mouthpiece and Applicant's invention to perform equally well with either mouthpiece designs.

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9. Applicant's arguments, see page 23, lines 13-32, filed May 2, 2008 with respect to the rejection(s) of claim(s) 54, 55 and 57-60 under 35 USC 103(a) as being unpatentable over Mault over Hirsch have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of amended claim and newly found art.

10. Applicant's arguments, see page 24, line 22- page 25, line 6, filed May 2, 2008 with respect to the rejection(s) of claim(s) 61 under 35 USC 102(b) as being anticipated by Mault have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of amended claim and newly found art.

***Claim Rejections - 35 USC § 103***

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 1, 4-10 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,468,222 to Mault et al (Hereinafter "Mault") in view of US 6,319,199 to Sheehan et al (Hereinafter "Sheehan") and US 4,233,842 to Raemer et al (Hereinafter "Raemer").

In reference to claims 1, 7, 9 and 12:

Mault teaches:

A calorimeter for measuring the metabolic rate of a subject, which comprises a symmetrical housing and base (12 of Mault) to be gripped by an operator, which has a front edge (the same side display 18 of Mault) and an opposite back edge (the same side as mouthpiece 14). The device further comprises a display (18 of Mault) oriented on one of the edges and aligned with an operator's direct line of view while gripping the base (Fig. 1 of Mault). A mouthpiece interface (32 of Mault) is used for interfacing with a removable mouthpiece, wherein the mouthpiece interface is oriented with respect to the base such that when the operator stands in front of the subject and a subject blows into the mouthpiece the display is not in the direct line of view of the subject (Fig. 1 of Mault). An actuator including a manual sample button (16 of Mault) is located on the edge adjacent to the display. The discard breath is not directed at the operator (port G, and 72 of Mault).

However, Mault fails to teach that:

The actuator is located on the edge of the base opposite the display and an alcohol sensor is fluidly connected to the

mouthpiece interface. The alcohol sensor being adapted to detect alcohol present in the subject by the subject blowing into the mouthpiece.

Sheehan teaches:

A portable data collection device for diagnosing and data collection (Abstract of Sheehan) comprising actuator buttons placed on the same (216 of Sheehan) or opposite (218 of Sheehan) side of the display (220 of Sheehan). The input dials (216 and 218 of Sheehan) control the operation of the device.

Therefore it would have been obvious to one having ordinary skill in the art at the time the applicant's invention was made to have placed the operating actuator buttons on the gripping handle of the device, similar to the teachings of Sheehan, in the Calorimeter of Mault, in order to allow the subject more convenience while operating the device.

However, the combination fails to teach that:

An alcohol sensor is fluidly connected to the mouthpiece interface, the alcohol sensor being adapted to detect alcohol present in the subject by the subject blowing into the mouthpiece.

Raemer teaches:

An apparatus used for detection and measurement of selected fluids in expired air taken from a living individual (Fig. 1 of Raemer) which comprises a sensors (22 and 13 of Raemer). The



system is capable of detecting different respiratory fluids based on the measurement of CO<sub>2</sub> and O<sub>2</sub> levels, such as the metabolic rate of the subject or anesthetic vapors or blood alcohol of the user (Col. 5, lines 13-28 and Col. 6, lines 41-58 of Raemer).

Therefore it would have been obvious to one having ordinary skill in the art at the time the applicant's invention was made to have modified the metabolic calorimeter of Mault as modified by Sheehan to be able to measure other expiratory fluids, such as blood alcohol or anesthetic vapors, as taught by Raemer in order to be able to detect and measure different types of fluid in the exhaled breath of an individual.

In reference to claim 4:

The housing assembly comprises a first sidewall (the side towards 74 of Mault) and an opposite second sidewall (26 of Mault) coupled together at a front edge (the edge towards element 34 of Mault) and a back edge (the connection edge on the opposite side). The first and second sidewalls are extended radially between a top surface (the side towards 68 of Mault) and a bottom surface (the side towards 70 of Mault). The display is located along the front edge, and the mouthpiece interface is located along the top surface (Figs. 3 and 4 of Mault).

In reference to claims 5 and 6:

The mouthpiece interface is oriented with respect to the housing such that the mouthpiece extends outward from the housing back edge when the mouthpiece is coupled to the housing (Fig. 2 of Mault). The mouthpiece extends obliquely from the top surface and substantially parallel to the top surface (Figs. 21 and 24 of Mault).

The mouthpiece of Mault does not extend obliquely from the top surface and as disclosed in Figs. 2 and 4 it extends directly (perpendicular to the top surface) from the top surface of the housing. At the time the applicant's invention was made it would have been an obvious matter of design choice to a person of ordinary skill in the art to have placed the mouthpiece of Mault in an oblique position rather than a perpendicular position. Applicant has not disclosed that positioning the mouthpiece in a particular angle provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art would have expected Mault's mouthpiece and Applicant's invention to perform equally well with either mouthpiece positioned at an oblique or perpendicular angle. Therefore it would have been obvious to modify Mault to obtain the invention as specified in claims 5 and 6 because such modifications would have been considered a mere design choice which fails to patentably distinguish over the prior art of Mault.

In reference to claims 8 and 10:

An actuator (16 of Mault) is used for controlling illumination of a portion of the

housing. A light source illuminates at least a portion of the interface, where the housing has an opening for light to pass from an interior of the housing to an exterior of the housing for illuminating at least a portion of the interface (Col. 3, line 59- Col. 4, line 5 of Mault).

13. Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mault in view of Sheehan and Raemer as applied to claim 1 above, and further in view of US 5,291,898 to Wolf (Hereinafter "Wolf").

In reference to claim 11:

Mault, as modified by Sheehan and Raemer, teaches all of the claim limitations; See the rejection of claim 1 above.

However, the combination fails to teach that:

The housing comprises a mouthpiece ejector for facilitating removal of the mouthpiece from the housing.

Wolf teaches:

A hand held device for measuring breath alcohol which comprises an ejector (120 of Wolf) for ejecting the mouthpiece forceably so that the mouthpiece is ejected into a refuse container or onto the ground without the need of the officer administering the test to touch the used mouthpiece (Col. 9, lines 9-17 of Wolf).

Therefore it would have been obvious to one having ordinary skill in the art at the

time the applicant's invention was made to have added an ejector, similar to the one taught by Wolf, in the calorimeter level measurement device of Mault, as modified by Sheehan and Raemer, in order to prevent the operator from touching the used mouthpiece after it has been used by the subject.

14. Claims 13 and 15-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,274,425 to Lutz et al (Hereinafter "Lutz") in view of Mault.

In reference to claims 13 and 15-16:

Lutz teaches:

A device for measuring redox gases, such as alcohol, in a person's breath, which comprises a disposable mouthpiece (Abstract of Lutz). The mouthpiece (5 of Lutz) comprises a first end (39 of Lutz) and a second end (27 of Lutz). The second end is closed and is rounded to facilitate engagement with the breath testing device (Fig. 1 of Lutz). The mouthpiece further comprises at least one port for channeling air blown into the mouthpiece (through 39 and 15 of Lutz) into the breath testing device. The mouthpiece is made of plastic material (Col. 1, lines 48-50 of Lutz). The mouthpiece snaps into engagement with the breath testing device (snap members 23, 25, 33 and 35 and Col. 3, lines 40-52 of Lutz). A stop member (the bend at 41 of Lutz) extending radially outward from the body to facilitate positioning a subject's mouth during breath testing (Fig. 1

of Lutz).

However, Lutz fails to teach that:

The mouthpiece has a cross-sectional shape being one of: a D-shaped cross-sectional shape and a V-shaped cross-sectional shape.

Mault teaches:

A calorimeter used for measuring the metabolic rate of a subject which comprises a symmetrical housing and base (12 of Mault) to be gripped by an operator (the same side display 18 of Mault). The housing further comprises a mouthpiece interface sized to receive a mouthpiece in sealing contact therein (the inlet port 346 of Mault creates an airtight seal). A portion of the mouthpiece body has a selected cross-sectional shape being one of a D-shaped cross-sectional shape or a V-shaped cross-sectional shape (Fig. 23 of Mault discloses a D-shape cross-section).

The mouthpiece of Mault has a substantially D-shape but however Mault does not disclose a V-shape cross-section. At the time the applicant's invention was made it would have been an obvious matter of design choice to a person of ordinary skill in the art to have used a different design for the mouthpiece of Mault such as a mouthpiece with a V-shape cross-section rather than a D-shape cross-section. Applicant has not disclosed that choosing a V-shape

cross-section for the mouthpiece provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art would have expected Mault's mouthpiece and Applicant's invention to perform equally well with either mouthpiece designs.

Therefore it would have been obvious to one having ordinary skill in the art at the time the applicant's invention was made to have replaced the mouthpiece of Lutz with a mouthpiece similar to the one taught by Mault in order to collect breath samples from the subject for further analysis. Substituting one known element with another would have yielded predictable results. It would have been obvious to modify Mault to obtain the invention as specified in claims above because such modifications would have been considered a mere design choice which fails to patentable distinguish over the prior art of Mault.

15. Claims 23-24, 26-32, 34, 36-42, 44, 45, 47-48, 50-53 and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mault in view of Raemer.

In reference to claims 23-24 and 29-30:

Mault teaches:

A calorimeter for measuring the metabolic rate of a subject which

comprises housing (10 of Mault), which comprises a base (12 of Mault), a display (18 of Mault), and a mouthpiece interface (14 or 20 of Mault). The base can be gripped by an operator during testing, and the display is oriented with respect to the housing to be in line with an operator's direct line of view while gripping the base (Fig. 1 of Mault). The mouthpiece is removably coupled to the mouthpiece interface (346 in Fig. 23 and 326 in Fig. 21 of Mault). The mouthpiece comprises at least one substantially planar surface (Fig. 23 of Mault). The mouthpiece interface includes a stop for positively locating the mouthpiece (the ring around the connection 332 of Mault). The mouthpiece is placed against the stop in a testing position (Fig. 21 of Mault). The housing further comprises at least one actuator for controlling operation of the breath tester (16 of Mault). The mouthpiece is further oriented with respect to the housing such that discard breath discharged from the housing is not directed at the operator (Fig. 4 and output port G, or 72 of Mault).

However, Mault fails to teach that:

An alcohol sensor is fluidly connected to the mouthpiece interface, the alcohol sensor being adapted to detect alcohol present in the subject by the subject blowing into the mouthpiece.

Raemer teaches:

An apparatus used for detection and measurement of selected fluids in expired air taken from a living individual (Fig. 1 of Raemer) which comprises sensors (22 and 13 of Raemer). The system is capable of detecting different respiratory fluids based on the measurement of CO<sub>2</sub> and O<sub>2</sub> levels, such as the metabolic rate of the subject or anesthetic vapors or blood alcohol of the user (Col. 5, lines 13-28 and Col. 6, lines 41-58 of Raemer).

Therefore it would have been obvious to one having ordinary skill in the art at the time the applicant's invention was made to have modified the metabolic calorimeter of Mault to be able to measure other expiratory fluids, such as blood alcohol or anesthetic vapors, as taught by Raemer in order to be able to detect and measure different types of fluid in the exhaled breath of an individual.

In reference to claims 26-28:

The housing assembly comprises a first sidewall (the side towards 74 of Mault) and an opposite second sidewall (26) coupled together at a front edge (the edge towards element 34 of Mault) and a back edge (the connection edge on the opposite side). The first and second sidewalls are extended radially between a top surface (the side towards 68) and a bottom surface (the side towards 70 of Mault). The display is located along the front edge, and the mouthpiece interface is located along the top surface (Figs. 3 and 4 of Mault). The mouthpiece



interface is further oriented obliquely from the top surface and is substantially parallel to the top surface (Figs. 21 and 23 of Mault). The housing further comprises a mouthpiece interface sized to receive a mouthpiece in sealing contact therein (the inlet port 346 of Mault creates an airtight seal). The mouthpiece comprises one of a tube and a funnel (Fig. 23 of Mault).

The mouthpiece of Mault does not extend obliquely from the top surface and as disclosed in Figs. 2 and 4 it extends directly (perpendicular to the top surface) from the top surface of the housing. At the time the applicant's invention was made it would have been an obvious matter of design choice to a person of ordinary skill in the art to have placed the mouthpiece of Mault in an oblique position rather than a perpendicular position. Applicant has not disclosed that positioning the mouthpiece in a particular angle provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art would have expected Mault's mouthpiece and Applicant's invention to perform equally well with either mouthpiece positioned at an oblique or perpendicular angle. Therefore it would have been obvious to modify Mault to obtain the invention as specified in claims above because such modifications would have been considered a mere design choice which fails to patentably distinguish over the prior art of Mault.

In reference to claims 36-37, 40-42 and 61:

Mault teaches:

A calorimeter used for measuring the metabolic rate of a subject which comprises a symmetrical housing and base (12 of Mault) to be gripped by an operator, which has a front edge (the same side display 18 of Mault) and an opposite back edge (the same side as mouthpiece 14). The device further comprises a display (18 of Mault) oriented on one of the edges and aligned with an operator's direct line of view while gripping the base (Fig. 1 of Mault). A mouthpiece interface (32 of Mault) is used for interfacing with a removable mouthpiece, wherein the mouthpiece interface is oriented with respect to the base such that when the operator stands in front of the subject and a subject blows into the mouthpiece the display is not in the direct line of view of the subject (Fig. 1 of Mault). The housing assembly comprises a first sidewall (the side towards 74 of Mault) and an opposite second sidewall (26) coupled together at a front edge (the edge towards element 34 of Mault) and a back edge (the connection edge on the opposite side). The first and second sidewalls are extended radially between a top surface (the side towards 68) and a bottom surface (the side towards 70 of Mault). The display is located along the front edge, and the mouthpiece interface is located along the top surface (Figs. 3 and 4 of Mault). The mouthpiece interface is further oriented obliquely from the top surface and is substantially parallel to the top

surface (Figs. 21 and 23 of Mault). The housing further comprises a mouthpiece interface sized to receive a mouthpiece in sealing contact therein (the inlet port 346 of Mault creates an airtight seal). The mouthpiece comprises one of a tube and a funnel (Fig. 23 of Mault).

The mouthpiece of Mault does not extend obliquely from the top surface and as disclosed in Figs. 2 and 4 it extends directly (perpendicular to the top surface) from the top surface of the housing. At the time the applicant's invention was made it would have been an obvious matter of design choice to a person of ordinary skill in the art to have placed the mouthpiece of Mault in an oblique position rather than a perpendicular position. Applicant has not disclosed that positioning the mouthpiece in a particular angle provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art would have expected Mault's mouthpiece and Applicant's invention to perform equally well with either mouthpiece positioned at an oblique or perpendicular angle. Therefore it would have been obvious to modify Mault to obtain the invention as specified in claims above because such modifications would have been considered a mere design choice which fails to patentably distinguish over

the prior art of Mault.

However, Mault fails to teach that;

An alcohol sensor is fluidly connected to the mouthpiece interface, the alcohol sensor being adapted to detect alcohol present in the subject by the subject blowing into the mouthpiece.

Raemer teaches:

An apparatus used for detection and measurement of selected fluids in expired air taken from a living individual (Fig. 1 of Raemer), which comprises a sensors (22 and 13 of Raemer). The system is capable of detecting different respiratory fluids based on the measurement of CO<sub>2</sub> and O<sub>2</sub> levels, such as the metabolic rate of the subject or anesthetic vapors or blood alcohol of the user (Col. 5, lines 13-28 and Col. 6, lines 41-58 of Raemer).

Therefore it would have been obvious to one having ordinary skill in the art at the time the applicant's invention was made to have modified the metabolic calorimeter of Mault to be able to measure other expiratory fluids, such as blood alcohol or anesthetic vapors, as taught by Raemer in order to be able to detect and measure different types of fluid in the exhaled breath of an individual.

In reference to claims 31-32 and 38-39:

The housing comprises one actuator (16) for controlling illumination of a portion

of the housing. A light source is used for illuminating at least a portion of the interface, where an opening on the housing will pass light from an interior to an exterior of the housing (Col. 3, line 59-Col. 4, line 5 of Mault).

In reference to claims 34 and 45:

A portion of the body has a selected cross-sectional shape being one of a D-shaped cross-sectional shape and a V-shaped cross-sectional shape (Fig. 23 of Mault discloses a D-shape cross-section.

The mouthpiece of Mault has a substantially D-shape but however Mault does not disclose a V-shape cross-section. At the time the applicant's invention was made it would have been an obvious matter of design choice to a person of ordinary skill in the art to have used a different design for the mouthpiece of Mault such as a mouthpiece with a V-shape cross-section rather than a D-shape cross-section. Applicant has not disclosed that choosing a V-shape cross-section for the mouthpiece provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art would have expected Mault's mouthpiece and Applicant's invention to perform equally well with either mouthpiece designs. It would have been obvious to modify Mault to obtain the invention as specified in claims above because such modifications would have been considered a mere design choice which fails to patentably distinguish over the prior art of Mault.

In reference to claim 44:

A portion of the mouthpiece has a cross-sectional shape that is substantially similar to at least portion of a cross-sectional shape defined by the mouthpiece interface, such that the mouthpiece interface facilitates positioning the mouthpiece in proper alignment with respect to the housing (the inlet port 346 of Mault and the narrower side of the funnel 344 of Mault have the same cross section).

In reference to claim 47:

Mault teaches a calorimeter for measuring the metabolic rate of a subject, which comprises a mouthpiece (14 or 20 of Mault). The mouthpiece comprises a first end (seal 354 of Mault), a second end (the end attached to 346 of Mault), and a body extending there between (344 of Mault). A portion of the body has a selected cross-sectional shape being one of a D-shaped cross-sectional shape and a V-shaped cross-sectional shape (Fig. 23 of Mault discloses a D-shape cross-section. The body further comprises a passageway extending through the body from the first end towards the second end (Fig. 24 of Mault), where the passageway channels the air blown into the mouthpiece into the breath testing device (Fig. 4 of Mault).

The mouthpiece of Mault has a substantially D-shape but however Mault does not disclose a V-shape cross-section. At the time the applicant's invention was made it would have been an obvious matter of design choice to a person of

ordinary skill in the art to have used a different design for the mouthpiece of Mault such as a mouthpiece with a V-shape cross-section rather than a D-shape cross-section. Applicant has not disclosed that choosing a V-shape cross-section for the mouthpiece provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art would have expected Mault's mouthpiece and Applicant's invention to perform equally well with either mouthpiece designs. It would have been obvious to modify Mault to obtain the invention as specified in claim 47 because such modifications would have been considered a mere design choice which fails to patentably distinguish over the prior art of Mault.

In reference to claims 48 and 50-53:

The body further comprises an external surface (the outside surface of 344 of Mault), an internal surface (internal surface of 344 of Mault), and at least one inlet port (30 of Mault) extending there between. The inlet port channels air from the passageway into the breath testing device (Fig. 4 of Mault). The mouthpiece comprises a substantially planar surface (Fig. 24 of Mault). One of the first end and the second end is rounded to facilitate engagement with the breath testing device (the connection 346 of Mault to the second end of the mouthpiece).

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16. Claims 25 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mault in view of Raemer as applied to claims 23 and 36 above, and further in view of Sheehan.

In reference to claims 25 and 43:

Mault, as modified by Raemer, teaches all of the claim limitations; see the rejections of claim 23 and 36 above.

However the combination fails to teach that:

The manual sample button is located on an edge of the housing base that is opposite an edge where the display is located.

Sheehan teaches:

A portable data collection device for diagnosing and data collection (Abstract of Sheehan) comprising actuator buttons placed on the same (216 of Sheehan) or opposite (218 of Sheehan) sides of the display (220 of Sheehan). The input dials (216 and 218 of Sheehan) control the operation of the device.

Therefore it would have been obvious to one having ordinary skill in the art at the time the applicant's invention was made to have placed the operating actuator buttons on the gripping handle of the device, similar to the teachings of Sheehan, in the Calorimeter of Mault as modified by Raemer, in order to give the subject more convenience while operating the device.



17. Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mault in view of Raemer as applied to claim 23 above, and further in view of Wolf.

In reference to claim 33:

Mault, as modified by Reamer teaches all of the claim limitations; see the rejection of claim 23 above.

However, the combination fails to teach that:

The housing comprises a mouthpiece ejector for facilitating removal of the mouthpiece from the housing.

Wolf teaches:

A hand held device for measuring breath alcohol which comprises an ejector (120 of Wolf) for ejecting the mouthpiece forceably, so that the mouthpiece is ejected into a refuse container or onto the ground without the need of the officer administering the test to touch the used mouthpiece (Col. 9, lines 9-17 of Wolf).

Therefore it would have been obvious to one having ordinary skill in the art at the time the applicant's invention was made to have added an ejector, similar to the one taught by Wolf, in the calorimeter level measurement device of Mault as modified by Raemer in order to prevent the operator from touching the used mouthpiece after it has been used by the subject.

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18. Claims 35, 46 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mault in view of Raemer as applied to claims 23 and 36 above, and further in view of Lutz.

In reference to claims 35 and 46:

Mault, as modified by Raemer, teaches all of the claim limitations; see the rejections of claims 23 and 36 above.

However, the combination fails to teach that:

The first end of the mouthpiece body is closed and an opposed second end of the body is open to enable a subject being tested to blow air into the body; that the body further comprises at least one port for blown air to pass through the port; and that the first end has a semi-circular cross-sectional profile.

Lutz teaches:

A device for measuring redox gases, such as alcohol, in a person's breath, which comprises a disposable mouthpiece (Abstract of Lutz). The mouthpiece (5 of Lutz) comprises a second end (39 of Lutz) and a first end (27 of Lutz). The second end is closed and rounded to facilitate engagement with the breath testing device (Fig. 1 of Lutz). The mouthpiece has a substantially semi-circular (the cross-section at 27 of Lutz).

Therefore it would have been obvious to one having ordinary skill in the art

at the time the applicant's invention was made to have substituted the mouthpiece of the metabolic calorimeter of Mault with a mouthpiece similar to the one taught by Lutz, in order to test the breath gases of a subject. The substitution of one known element in the art with another would have yielded predictable results.

In reference to claim 49:

The body further comprises an external surface (The outside surface of mouthpiece 5 of Lutz), an internal surface (inside surface of mouthpiece 5 of Lutz), and at least one outlet port (39 and 15 of Lutz) extending there between, where the outlet port channels discard breath air from the mouthpiece during testing.

19. Claim 54-55 and 57-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mault in view of Lutz.

In reference to claims 54-55 and 57-60:

Mault teaches:

A calorimeter for measuring the metabolic rate of a subject which comprises a mouthpiece (14 or 20 of Mault). The mouthpiece comprises a first end (seal 354 of Mault), a second end (the end attached to 346 of Mault), and a body extending there between

(344 of Mault). A portion of the body has a selected cross-sectional shape being one of a D-shaped cross-sectional shape and a V-shaped cross-sectional shape (Fig. 23 of Mault discloses a D-shape cross-section. The design of the mouthpiece or using an entirely different shape mouthpiece would not change the functionality of the claimed invention. The body further comprises a passageway extending through the body from the first end towards the second end (Fig. 24 of Mault), where the passageway channels the air blown into the mouthpiece into the breath testing device (Fig. 4 of Mault). The port is defined within the second body portion for channeling air blown into the first end into the breath testing device during testing (inlet port 30 of Mault). One of the first end and the second end is rounded to facilitate engagement with the breath testing device (the connection 346 of Mault to the second end of the mouthpiece). One of the first body portion and the second body portion has a substantially semi-circular cross-sectional shape (Fig. 24 of Mault).

The mouthpiece of Mault has a substantially D-shape but however Mault does not disclose a V-shape cross-section. At the time the applicant's invention was made it would have been an obvious matter of design choice to a person of ordinary skill in the art to have used a different design for the mouthpiece of Mault such as a

mouthpiece with a V-shape cross-section rather than a D-shape cross-section. Applicant has not disclosed that choosing a V-shape cross-section for the mouthpiece provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art would have expected Mault's mouthpiece and Applicant's invention to perform equally well with either mouthpiece designs. It would have been obvious to modify Mault to obtain the invention as specified in claims above because such modifications would have been considered a mere design choice which fails to patentably distinguish over the prior art of Mault.

However, Mault fails to teach that:

One port is defined within the first body portion for channeling discard breath air from the mouthpiece during testing, and it is oriented with respect to the mouthpiece such that discard breath is not directed towards an operator of the breath testing device during testing. The second end of the mouthpiece is closed, while the first end is open to enable a subject being tested to blow air into the mouthpiece.

Lutz teaches:

A device for measuring redox gases, such as alcohol, in a person's breath, which comprises a disposable mouthpiece (Abstract of Lutz). The mouthpiece (5 of Lutz) comprises a second end (39 of

Lutz) and a first end (27 of Lutz). The second end is closed and rounded to facilitate engagement with the breath testing device (Fig. 1 of Lutz). The mouthpiece has a substantially semi-circular (the cross-section at 27 of Lutz). Lutz also discloses that the exhaled air is passed through an opening (15 of Lutz) in order to be analyzed by the alcohol sensors to detect the blood alcohol levels of the user (Fig. 2 and Col. 3, lines 26-53 of Lutz).

It would have been obvious to one having ordinary skill in the art at time the applicant's invention was made to have substituted the mouthpiece of the metabolic calorimeter of Mault with a mouthpiece similar to the one taught by Lutz, in order to test the breath gases of a subject. The substitution of one known element in the art with another would have yielded predictable results.

### ***Double Patenting***

20. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422

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F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

21. Claims 13, 15-16, 23-27, 47-55 and 57-61 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 and 11-29 of copending Application No. 11/089,655. Although the conflicting claims are not identical, they are not patentably distinct from each other because both co-pending applications are drawn to a breathalyzer, which comprises housing and a mouthpiece with the same features indicated in claims above.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Conclusion***

22. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 4,656,008 to Gump discloses an alcohol breath testing device. US 2006/0206034 to Stock et al, discloses a breath alcohol monitor.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anita Saidi whose telephone number is (571)270-3001. The examiner can normally be reached on Monday-Friday 9:30 am - 6:00 pm Est.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Charles A. Marmor, II/  
Supervisory Patent Examiner  
Art Unit 3735

/A. S./  
Examiner, Art Unit 3735  
5/29/2008